Plan to Plan enrollment reconciliation… without burdening the pharmacy

During the start up phase of the Medicare Prescription Drug Program, CMS advised plans to delay processing of certain disenrollments. This was important to ensure that all enrolled beneficiaries, particularly dual-eligible beneficiaries who switched plans late in the process, could be assured access to prescription drug coverage. As a result of the January instructions from CMS, some plans continued delaying disenrollments and certain beneficiaries have had access to coverage under more than one plan: the initial plan that continued coverage, and a subsequent plan chosen by the beneficiary or an agent acting on their behalf (the legal "plan of record"). As a result, some plans may have paid for prescriptions for some beneficiaries who have switched plans or otherwise may not have been appropriately enrolled in the plan.

Now that systems are stabilized, we have to make sure Medicare beneficiaries are in one plan, and that claims paid inappropriately by another plan, are reconciled with the plan of record. Due to the volume of claims needing re-adjudication, pharmacy reversal and rebilling would impose a significant administrative and financial burden on pharmacies. To avoid placing any additional burdens on pharmacies in this process, we have established a plan to plan enrollment and reconciliation process that will occur over the next few weeks.

… finalizing the process

CMS is now taking steps to ensure that all beneficiaries who changed plans are appropriately disenrolled from their initial plan by April 30, 2006. The special enrollment reconciliation is a 3-step process that includes (1) beneficiary notice of disenrollment, (2) an opportunity to confirm enrollment in the plan of record or to re-enroll in the initial plan, and (3) payment reconciliation between plans. Of course, dual-eligible beneficiaries can choose to re-enroll in their original plan at any time, before and after this process. And all beneficiaries will continue to receive drug coverage through this process, either through the plan of record (which is already covering them) or through their initial plan. However, because some beneficiaries have continued to use services in their original plan and may prefer to continue in it, these beneficiaries will have a special opportunity to elect to do so.

What pharmacists need to know…

If a beneficiary enrolled in a second plan and never used the benefits of the initial plan, they will be automatically disenrolled from the initial plan by March 31. All other beneficiaries in multiple plans will receive a letter from a plan on CMS letterhead that explains what they need to do. A beneficiary who has continued to access benefits under their initial plan, but who has later enrolled in another plan (on their own, by someone else or by a state), will be disenrolled from the initial plan effective April 30, 2006 unless they contact the plan or Medicare. Letters will be sent by March 27, 2006 (letters attached).

Beneficiaries may ask their pharmacist what to do. Our advice is to keep it simple: The pharmacist should tell the beneficiary what plan the pharmacy has been billing for the beneficiary's prescriptions:

(1) <u>If plan name on the letter does not match the plan that the pharmacy has been billing</u> and the beneficiary is happy with the plan the pharmacy has been billing, the beneficiary needs to do nothing to stay in the plan the pharmacy has on record.

(2) <u>If the plan name on the letter matches the plan that the pharmacy has been billing</u> and the beneficiary wants to stay in that plan, the beneficiary will have to follow the instructions on the letter and call the plan to avoid disenrollment from that plan.

Beneficiaries with questions can be directed to call 1-800 MEDICARE and tell the operator that they have received the "Special Notice to Confirm Medicare Plan Choice".

HHS Announces More Than 27 Million Are Enrolled in Prescription Drug Coverage

HHS announced on Thursday that 1.9 million additional beneficiaries have signed up for prescription drug coverage since mid-February. This represents a 25 percent increase over last month in the number of people who have selected a plan and brings the total of those who have signed up individually over the past four months to approximately 7.2 million. "We are very pleased that more and more people with Medicare are taking advantage of this important benefit. Strong and steady enrollment has continued this month, with 380,000 Medicare beneficiaries signing up each week," HHS Secretary Mike Leavitt said. "Over 27 million beneficiaries are now getting coverage and saving money on their prescription drugs. We are well on the way to achieving our goal of 28 to 30 million enrollees in the first year."

Please see the HHS press release (http://www.hhs.gov/news/press/2006pres/20060323.html) for more information, including a state by state breakdown of enrollment numbers.

Click here www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/cedata032006.zip for enrollment data by county.

Final 2007 Formulary Guidance just released

CMS has released its final guidance on how we will review 2007 Medicare prescription drug benefit plans to assure that beneficiaries receive clinically appropriate medications at the lowest possible cost. The Guidance (Final CY 2007 Formulary Guidance.pdf) and a list of changes from the draft guidance (Formulary Guidance 2007 - Draft to Final.pdf) are attached.

** If the links above do not work, please copy and paste them into your browser.

SPECIAL NOTICE TO CONFIRM MEDICARE PLAN CHOICE

<Date>

Dear <Name of Member>:

The purpose of this notice is to confirm your choice of a Medicare prescription drug plan and to ensure that you are enrolled in the plan you want.

You have received Medicare prescription drug benefits or other Medicare services from [<Name of plan>]. However, Medicare's records show that you are now enrolled in a different plan. You either enrolled in this new plan on your own, or were enrolled by someone on your behalf, such as your State or your retiree health plan.

Please follow the steps below to be sure you are covered by the plan you want. **Remember that no matter what choice you make, you will not lose your Medicare prescription drug coverage.**

1. If you want to stay in [Name of Plan]:

If you want to stay in [Name of Plan] you must call [**INSERT**: the customer service number on the back of your membership card] **OR** [<1-xxx-xxx-xxxx>], no later than **[INSERT: Date] (Note to Plans—Please insert date on or after April 10 that will permit you to submit enrollment to CMS by April 15.)**. If you do not call [Name of Plan] by that date, you will no longer be able to use your membership card.

2. If you want to be covered by the plan in the Medicare records:

If you want to be covered by the plan shown in the Medicare records, you do not need to do anything. You should have received a membership card for this plan, and you can use your card to cover your prescriptions. **You will be enrolled in original Medicare for all other Medicare services.** If you want to contact the plan, you can call the customer service number on the back of the card, or 1-800-MEDICARE (1-800-633-4227). **However, you do not need to contact the plan to confirm your enrollment.**

3. If you are not sure which plan you are in:

If you are not sure which plan you are enrolled in, or if you have other questions about plans available in your area, you may call us at 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY/TDD users should call 1-877-486-2048. When you

call, please tell the operator that you have received this "Special Notice to Confirm Medicare Plan Choice."

Again, no matter what choice you make, you still have Medicare prescription drug coverage. And, you can still change plans at any time until May 15, 2006, if you find that the plan you have chosen does not meet your needs.

Thank you. We appreciate your attention to this matter.

SPECIAL NOTICE TO CONFIRM MEDICARE PLAN CHOICE

<Date>

Dear <Name of Member>:

The purpose of this notice is to confirm your choice of a Medicare prescription drug plan and to ensure that you are enrolled in the plan you want.

You have received Medicare prescription drug benefits from [<Name of plan>]. However, Medicare's records show that you are now enrolled in a different plan. You either enrolled in this new plan on your own, or were enrolled by someone on your behalf, such as your State or your retiree health plan.

Please follow the steps below to be sure you are covered by the plan you want. **Remember that no matter what choice you make, you will not lose your Medicare prescription drug coverage.**

1. If you want to stay in [Name of Plan]:

If you want to stay in [Name of Plan] you must call [**INSERT**: the customer service number on the back of your membership card] **OR** [<1-xxx-xxx-xxxx>], no later than **[INSERT: Date] (Note to Plans—Please insert date on or after April 10 that will permit you to submit enrollment to CMS by April 15.)**. If you do not call [Name of Plan] by that date, you will no longer be able to use your membership card.

2. If you want to be covered by the plan in the Medicare records:

If you want to be covered by the plan shown in the Medicare records, you do not need to do anything. You should have received a membership card for this plan, and you can use your card to cover your prescriptions. If you want to contact the plan, you can call the customer service number on the back of the card, or 1-800-MEDICARE (1-800-633-4227). **However, you do not need to contact the plan to confirm your enrollment.**

3. If you are not sure which plan you are in:

If you are not sure which plan you are enrolled in, or if you have other questions about plans available in your area, you may call us at 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY/TDD users should call 1-877-486-2048. When you call, please tell the operator that you have received this "Special Notice to Confirm Medicare Plan Choice."

Again, no matter what choice you make, you still have Medicare prescription drug coverage. And, you can still change plans at any time until May 15, 2006, if you find that the plan you have chosen does not meet your needs.

Thank you. We appreciate your attention to this matter.

[Letter for Use by Cost Plans with Part D Ben

SPECIAL NOTICE TO CONFIRM MEDICARE

<Date>

Dear <Name of Member>:

The purpose of this notice is to confirm your choice of a Medicare prescription drug plan and to ensure that you are enrolled in the plan you want.

You have received Medicare prescription drug benefits from [<Name of plan>]. However, Medicare's records show that you are now enrolled in a different plan. You either enrolled in this new plan on your own, or were enrolled by someone on your behalf, such as your State or your retiree health plan. You are still enrolled in [<Name of Cost Plan>] for your medical benefits.

Please follow the steps below to be sure you are covered by the plan you want. **Remember that no matter what choice you make, you will not lose your Medicare prescription drug coverage and you are still enrolled in [Name of cost plan] for your doctor and hospital coverage.**

1. If you want to stay in [Name of Plan] for your Medicare prescription drug coverage:

If you want to stay in [Name of Plan] you must call [**INSERT**: the customer service number on the back of your membership card] **OR** [<1-xxx-xxx-xxxx>], no later than **[INSERT: Date] (Note to Plans—Please insert date on or after April 10 that will permit you to submit enrollment to CMS by April 15.)**. If you do not call [Name of Plan] by that date, you will no longer be able to use your membership card at the pharmacy. Please also continue to use your membership card at the doctor's office.

2. If you want to be covered by the plan in the Medicare records for your Medicare prescription drug coverage:

If you want to be covered by the plan shown in the Medicare records, you do not need to do anything. You should have received a membership card for this plan, and you can use your card to cover your prescriptions. If you want to contact the plan, you can call the customer service number on the back of the card, or 1-800-MEDICARE (1-800-633-4227). **However, you do not need to contact the plan to confirm your enrollment.**

3. If you are not sure which plan you are in:

If you are not sure which plan you are enrolled in, or if you have other questions about Medicare prescription drug plans available in your area, you may call us at 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY/TDD users

should call 1-877-486-2048. When you call, please tell the operator that you have received this "Special Notice to Confirm Medicare Plan Choice."

Again, no matter what choice you make, you still have Medicare prescription drug coverage. And, you can still change plans at any time until May 15, 2006, if you find that the plan you have chosen does not meet your needs.

Thank you. We appreciate your attention to this matter.

MEDICARE MODERNIZATION ACT
2007 FINAL GUIDELINES -- FORMULARIES
CMS Strategy for Affordable Access to Comprehensive Drug Coverage

Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures

1. Purpose of the Guidance

This paper is final guidance on how CMS will review Medicare prescription drug benefit plans to assure that beneficiaries receive clinically appropriate medications at the lowest possible cost. Two key requirements in the Medicare Modernization Act (MMA) are to assure that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries, and to encourage and support the use of approaches to drug benefit management that are proven and in widespread use in prescription drug plans today. The goal is for plans to provide high-quality cost-effective drug benefits by negotiating the best possible prices and using effective drug utilization management techniques. This goal can be achieved through a review by CMS that facilitates appropriate beneficiary access to all medically necessary Part D covered drugs along with plan flexibility to develop efficient benefit designs, thus bringing drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population.

2. Strategic Approach

A. P & T Committee Review

We believe that current best practices for P&T committees should be applied when developing and administering P&T committees for the Medicare drug benefit. Incorporating best practice philosophies, along with inclusion of the MMA requirements, allows for a drug benefit that is clinically robust.

The requirements listed below are represented as 'BP' for best practice (or Industry Standard Practice) where they have been drawn from commercial best practices consistent with these nationally recognized P&T guidelines, and are represented as 'MMA' where the requirements support the unique provisions of the MMA.

Membership

- P&T committee members must come from various clinical specialties that adequately represent the needs of plans beneficiaries (i.e., include representation of "high volume specialists" in the standard terminology of the industry). (BP)
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both. (BP)
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons. (MMA)
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the plan and pharmaceutical manufacturers. (MMA)

Conflict of Interest

- P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions. (BP)

Meeting Administration

- P&T committee should meet on a regular basis, and not less frequently than on a quarterly basis. (BP)
- P&T committee decisions regarding formulary development or revision must be documented in writing. (BP)

Formulary Management

- P&T committee must review for clinical appropriateness, the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access. (BP)
- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy. (BP)
- The P&T committees will be required to establish and document procedures to assure appropriate drug review and inclusion. (BP)
- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies as well as other sources of appropriate information. (BP)
- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them into formulary tiers. (MMA)
- The P&T committee will make a reasonable effort to review a new chemical entity within 90 days, and will make a decision on each new chemical entity within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved. We set this timeframe in response to public comment on our proposed guidance for 2006, but note that plans must make access to new drugs available to enrollees when medically appropriate via exceptions processes even before this deadline. (BP)
- P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis. (MMA)
- Formulary therapeutic categories and classes may be changed only at the beginning of each plan year or when new drugs or new drug therapeutic uses appear. (MMA)

Formulary Exceptions

- P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. A non-formulary drug may be needed, for example, when the formulary drug would cause adverse effects or would not be as effective or both, based on scientific evidence or medical necessity. (BP)

B. Formulary Review

Approach

We encourage plans to submit formularies similar to those in widespread use today. We will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, to satisfy the MMA requirement that a plan's categorization system does not substantially discourage enrollment to any group of beneficiaries. We also will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Plans may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.

Review of Categories and Classes

We will review all classification systems to assure that plans provide an appropriate breadth of categories and classes that cover all disease states. CMS will not consider a classification system in isolation from the subsequent steps in our formulary review; a classification system with a smaller number of classes may be acceptable if it nonetheless provides preferred access to a relatively broad range of widely used medicines.

As described in the MMA, plans that utilize a classification system that is consistent with the USP classification system, available at www.usp.org, will satisfy a safe harbor and thus CMS will approve their formulary classification system. For plans that choose to adopt an alternative to USP's classification structure, CMS will check the plan's proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, information available at www.ashp.org/ahfs.

The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the classification system that is utilized. We view this requirement as a floor rather than an absolute standard. CMS may require more than two drugs per category or class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain disease states.

Even though a formulary may pass the classification review and have a safe harbor for its categories and classes, it still must undergo the drug list review and benefit management tools review in order to analyze the depth and breadth of drugs and their restrictions.

Drug List Review

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The following paragraphs describe the multiple checks that will be utilized as part of the drug list review.

1. CMS will review formularies for at least one drug in each of the Formulary Key Drug Types identified by USP. Best practice formularies commonly include at least one drug in each of the Formulary Key Drug Types as a minimum on their formulary. Plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each of the USP Formulary Key Drug Types. If a USP Formulary Key Drug Type only includes drugs that are primarily covered under Part B, it is not CMS' expectation that these Key Drug Types be represented on formularies. Similarly, if only over-the-counter (OTC) or statutorily excluded drugs, or drugs that were determined by the FDA to be less than effective (LTE), comprise a Key Drug Type, plans do not need to include representative drugs on the formulary. A list of Formulary Key Drug Types that are exempt from this drug list review check can be found in Appendix B.

2. CMS will review tier placement to provide an assurance that the formulary does not substantially discourage enrollment of certain beneficiaries. When developing their formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.

3. CMS will analyze formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines which are indicative of general best practice. Examples of these may include asthma, diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson's disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process. Drugs or drug classes

included within these widely accepted guidelines will not place undue burden on plans since these drugs are usually placed in favorable positions on commonly used, best practice formularies.

4. CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the general Medicare and the dually eligible population (Appendix A). This list is derived from the Medicare Current Beneficiary Survey (MCBS) data from 2002 and the Department of Health and Human Services Office of Inspector General (OIG) study: *Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs*. As with the MCBS data, the drugs identified by the OIG will be expanded to the class level, not the specific drug identified by the report. CMS understands that plans will not provide identical coverage of these drug classes, and our review will focus on assuring that plans present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow us to ensure that plans are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

C. Review of Benefit Management Tools that Affect Access

Approach

Prior Authorization, Step Therapy, and Quantity Limitations

CMS will look to existing best practices to check that plans' use of these utilization management tools is consistent with such practices. We will look to current industry standards as well as appropriate guidelines that might be found from expert organizations such as NCQA, AMCP, and NAIC, and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. CMS will assure that plans' use of such tools is consistent with best practices. CMS will also compare formularies amongst the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. Our expectation is that these techniques will be used in Part D formularies consistently with the way they are applied in existing formulary systems. In cases where a plan may fall outside of best practices, the plan will be asked to provide a reasonable justification for their practices.

All formularies will be evaluated using the criteria outlined above. Outliers for each area of review will be further evaluated by CMS to determine if the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that would cause discrimination. If any of the outliers appear to create problems of access, plans will have the opportunity to present reasonable clinical justifications.

3. Other Formulary Considerations

A. Long-term Care Accessibility

Part D plans will be required to provide medically necessary prescription drug treatments for the general Medicare population, as well as those beneficiaries who reside in long-term care (LTC) facilities. For example, it is CMS' expectation that plans provide coverage of dosage forms of drugs that are widely utilized in the LTC setting such as unit dose products, liquid, chewable, and parenteral preparations. Further, while nebulized solutions may not be required on all formularies, we would expect plans to also cover these dosage forms under circumstances in which Part B coverage does not exist. When determining days supplies for residents in LTC facilities, Part D plans should follow industry best practices and allow for at least 31 days per fill.

B. Specialty Tiers

Section 423.578(a)(7) of the Title I regulations allows Part D plans to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. In order to ensure that a Part D plan does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that comply with the following:

1. Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
2. Cost-sharing associated with the specialty tier is limited to 25% in the initial coverage range (or actuarially equivalent for plans with decreased or no deductible basic alternative benefit designs).
3. Only Part D drugs with plan negotiated prices that exceed $500 per month may be placed in the specialty tier.

If all drugs within a category or class meet the criteria for inclusion in the specialty tier, then a plan does not need to identify a preferred drug for that category or class.

C. Six Classes of Clinical Concern

For CY 2006, CMS required Part D plan formularies to include "all or substantially all" drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling with Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.

For CY 2007, CMS will continue to require Part D plan formularies to include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes in order to maintain the level of protection that is currently being provided to beneficiaries who are being treated with drugs from these six classes of clinical concern.

We expect formularies to include substantially all drugs in these six categories that are available on April 17, 2006. New drugs or newly approved uses for drugs within the six classes that come onto the market after April 17, 2006 will be subject to an expedited Pharmacy and Therapeutic committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.

"Substantially all" in this context means that all drugs and unique dosage forms in these categories are expected to be included in plan formularies, with the following exceptions:

- multi-source brands of the identical molecular structure
- extended release products when the immediate-release product is included
- products that have the same active ingredient
- dosage forms that do not provide a unique route of administration (e.g. tablets and capsules)

Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. If a plan cannot determine at the point of sale that an enrollee is not currently taking a drug (e.g. new enrollee filling a prescription for the first time), plans shall treat such enrollees as currently taking the drug. For beneficiaries who begin treatment with drugs in these categories other than HIV/AIDS drugs, plans may use these techniques to manage therapy. For HIV/AIDS drugs, the use of utilization management tools such as prior authorization and step therapy should be consistent with the 2006 policy. Plans may, of course, conduct consultations with physicians regarding treatment options and outcomes in all cases.

D. Submission of Multiple Formularies

CMS recognizes that plans may wish to submit more than one formulary in order to offer enhanced access to Part D drugs. We have the responsibility to ensure that there are meaningful differences between multiple formulary submissions from one organization to reduce confusion amongst beneficiaries. CMS may request that plans withdraw a formulary in which no meaningful differences can be demonstrated.

4. Formulary Submission Requirements

In support of the Medicare Modernization Act (MMA), CMS has established a systems interface within the Health Plan Management System (HPMS) to enable plans to submit their formularies electronically. This functionality provides for the upload and receipt of the formulary file, prior authorization, and step therapy supplemental data, as defined by CMS. It will also allow CMS to provide more timely, systematic, and consistent feedback to plans regarding their formulary practices.

Using the HPMS formulary upload module, all new and renewing contracts for 2007 are required to submit one or more formulary files between March 27, 2006 and April 17, 2006, 5:00pm EDT.

CMS will provide an opportunity for organizations to update formulary files prior to the beginning of the 2007 marketing period. The open period for these changes will occur from August 1-7, 2006. This will be the only opportunity to update formulary files prior to the beginning of the 2007 contract year.

Appendix A

Top Drug Classes

ACE inhibitors	Macrolides
Alpha-2 adrenergic agonists	Nitrates
Alpha blockers	Non-opioid analgesics
Angiotensin receptor blockers	Non-sedating antihistamines
Anticholinergic bronchodilators	Ophthalmic prostaglandins
Anticoagulants	Opioid analgesics
Antidyskinetics	Penicillins
Antiemetics	Platelet aggregation inhibitors
Antigout agents	Potassium sparing diuretics
Atypical antipsychotics	Potassium supplements
Beta-blockers	Proton pump inhibitors
Biguanides	Quinolones
Bisphosphonates	Sedatives
Calcium channel blockers	Selective estrogen receptor modifiers
Cardiac inotropes	Serotonin modifiers
Cephalosporins	Short-acting and intermediate-acting insulin mixtures
Cholesterol absorption inhibitors	Short-acting beta agonists
Cholinesterase inhibitors	Short-acting insulins
Corticosteroids	Skeletal muscle relaxants
Cox-2 inhibitors	Sodium channel inhibitors
Estrogens	SSRIs
GABA agents	Statins
Inhaled corticosteroid	Sulfonylureas
Intermediate-acting insulins	Thiazide diuretics
Intranasal corticosteroids	Thiazolidinediones
Laxatives	Thyroid replacements
Leukotriene modifiers	Tricyclic antidepressants
Long-acting beta agonists	Urinary Antispasmodics
Loop diuretics	

Appendix B

Formulary Key Drug Types Exempt From Drug List Review Check

Antiarhythmics (Other)
Osmotic Diuretics
Osmotic Agents, Ophthalmic
Parathyroid/Metabolic Bone Disease Agents (Other)
Retinal Agents, Ophthalmic

Final 2007 Formulary Guidance
Changes from Draft Guidance

CMS appreciates all of the public comments received in response to the draft 2007 formulary guidelines. In order to balance different viewpoints from various stakeholders and allow drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population, we have made the following modifications to the draft 2007 formulary guidance.

Drug List Review

- **CMS has included clarification of which Formulary Key Drug Types are exempt from the drug list review check.** Appendix B includes a table of Formulary Key Drug Types that are exempt from the drug list review check since these Key Drug Types are primarily covered under Part B.

Specialty Tiers

- **CMS has clarified that a specialty tier is not required on all formularies.** Formularies may choose to utilize a specialty tier within their formulary and benefit design, however, this is not a requirement.

Six Classes of Clinical Concern

- **CMS added a requirement for expedited P&T review for new drugs or newly approved uses for drugs within the six classes of clinical concern.** P&T committees are required to review new drugs or newly approved uses for drugs within the six classes that come onto the market after April 17, 2006 using an expedited review process. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.

Formulary Submission Requirements

- **CMS added detail regarding the update of formularies prior to the beginning of 2007 marketing.** The open period for these changes will occur from August 1-7, 2006. This will be the only opportunity to update formulary files prior to the beginning of the 2007 contract year.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

Date: March 21, 2006

To: Medicare Advantage, Prescription Drug Plan, Cost, PACE, and Demonstration Organizations

From: Gary Bailey, Deputy Director for Plan Policy and Operations

Subject: Enrollment Reconciliation Process – IMMEDIATE ACTION

The following instructions outline the enrollment reconciliation process to be followed by all plans. These instructions are consistent with the initial instructions released last on March 17, but we have clarified several items that prompted questions or concerns. Plans should already have commenced this process by analyzing the data files they received last week. Plans should continue with that process and move into the next phases of the enrollment reconciliation process.

In addition to outlining the enrollment reconciliation process, these instructions include two special disenrollment letters to be used for beneficiary communications. As stated below, these letters represent the only **outbound** communications plans shall have with beneficiaries impacted by this process. They shall only be used as directed below or by future instructions from CMS. The "PDP Letter-final.doc" file shall be used by all PDPs. That letter shall also be used by all MA-PDs in situations where the new plan of record is another MA-PD plan (indicated by an H number on the disenrollment file). The "MA-PD to PDP final.doc" file should be used by MA-PDs only in situations where the new plan of record is a PDP (indicated by an S number on the disenrollment file).

All letters are to be distributed on CMS letterhead, which is incorporated into the attached letters, both entitled “Special Notice to Confirm Medicare Plan Choice. Each letter includes several areas where the plan needs to insert information, such as the member's name and the name of the plan. In particular, note specific instructions related to inserting a date by which the member must contact the plan, included in the instructions below.

Enrollment Reconciliation Process
CMS distributed an enrollment reconciliation file on March 14, 2006. On March 22, CMS will distribute a full enrollment file to all plans. Plans must carefully follow the instructions for handling each of these files, and process the files in the manner prescribed here, in order to successfully complete the enrollment reconciliation process. The goal of this process is to ensure that people are enrolled properly AND that there is complete and up-to-date billing information available at the pharmacy. It is very important that plan files include complete and correct 4Rx information on all of these members.

The enrollment reconciliation file represents all beneficiaries that were transferred from one plan to another within MARx, and is distributed to the plans from which the beneficiaries were automatically disenrolled in the CMS system. This file is to be used only in support of the enrollment reconciliation effort, and NOT for marketing. All outbound communications to this group of beneficiaries shall be accomplished only as specified by these or future CMS instructions.

Step One

Plans shall first analyze the plan reconciliation file as compared with their enrollment/eligibility databases. For any beneficiary already shown as disenrolled on the plan databases, plans shall take no action. These individuals should already have received correspondence informing them of their disenrollment from the plan. Plans shall not mail any further correspondence to these beneficiaries regarding their enrollment status.

Step Two

For the beneficiaries that remain on the plans' enrollment files, plans must determine which of these beneficiaries have claims activity, medical (for MA-PD) or pharmacy.

For beneficiaries with no claims activity:

- Perform the routine disenrollment process under the following guidelines.
    - Do not mail the special disenrollment letter or any other correspondence to these beneficiaries regarding their enrollment status.
    - Deactivate these beneficiaries' pharmacy cards to prevent them from accessing plan benefits in the future.
    - If the disenrollment date on the CMS file differs from that on the plan database, update the plan database to reflect the official CMS date.

For beneficiaries with claims activity:

- **Do not** disenroll any of these beneficiaries until plans have taken specific steps to protect these beneficiaries' interests and continuity of benefits.

- Send the special disenrollment letter on CMS letterhead immediately upon identification of these beneficiaries.
    - These letters must be mailed no later than March 27, 2006.
    - These letters will advise beneficiaries of their option to remain with the original plan, and of the deadline for declaring their intent to do so, consistent with the plan's ability to submit enrollment transactions by April 15, 2006.
    - The attached letters instruct plans, under Item #1, to insert the date by which the member must contact you to enable you to submit a transaction to CMS by April 15. This date is at each plan's discretion, but must be no earlier than April 10.
    - Beneficiaries may indicate their intent to remain with the plan in writing or by telephone.

- For beneficiaries that declare their intent to stay with the plan, the plan must submit a retroactive transaction type 61 to CMS on or before April 15, 2006.
    - Plans must allow enough lead time in their instructions to beneficiaries to ensure submission of all transactions by April 15, 2006.

- Since transactions may have different effective dates (1/1/2006, 2/1/2006, and 3/1/2006), plans shall create one and only one file for each effective date
- **The transaction effective date shall be the later of 1) January 1, 2006 or 2) the day after the disenrollment date on the reconciliation file.**
- Further systems instructions regarding the specific requirements for submitting this file will be released later this week.
- For enrollees that elect to remain with the original plan after the April 15 retroactive transaction submission deadline, CMS will allow liberal use of special election periods to ensure the beneficiary is able to remain with the plan of their choice. However, transactions submitted to CMS after April 15 shall not be retroactive.

- For beneficiaries who take no further action, disenroll them by April 30, 2006 **effective back to the date of disenrollment on the enrollment reconciliation file.** Do not pay for any pharmacy benefits after April 30 for these beneficiaries.
  - **Do not reverse any claims for any of these beneficiaries. CMS will facilitate a plan to plan financial reconciliation process for this group of beneficiaries.** Further instructions will be forthcoming regarding the plan to plan reconciliation.
  - CMS will also distribute additional instructions regarding the provision of Explanations of Benefits (EOBs) to these beneficiaries and their plans.

- The plan shall continue to process pharmacy claims for any beneficiary who elects to remain in the plan while awaiting confirmation from CMS.

- The plan **shall not** execute the disenrollment in the plan system for beneficiaries who elect to remain with the plan.

Regardless of beneficiary category and action taken, plans should not send any disenrollment transactions to CMS solely as a result of this process. The individuals CMS has reported to plans as transferred are already disenrolled within CMS's databases. MARx will reject any plan-submitted disenrollment transactions for these beneficiaries.

Step Three

After following the disenrollment process outlined above, plans shall process the full enrollment file to complete the plans' enrollment and eligibility databases. Since the reconciliation process will complete the act of transferring beneficiaries from one plan to another, it is critical that the receiving plan have all active MARx enrollments on its databases, including active 4Rx files, before the original plan acts to disenroll a beneficiary that has been using its services (beneficiaries in the third group).

Since disenrollments for these beneficiaries will take effect on April 30, these beneficiaries must all have a benefit available to them in the receiving plan by May 1, 2006 to ensure continuity of benefits. Therefore, receiving plans must have a full roster of enrollments in their systems prior to April 30, 2006, and all beneficiaries must have active pharmacy cards and active "4Rx" files. Because plans have already received this enrollment information and because of the high level of matching between CMS and plan files for enrollees, we expect that plans have already taken these steps. Please confirm this is the case by reviewing the completeness of your eligibility and copayment information.

The full enrollment file will be in a TRR format with the TRC of 999. The rules for processing this enrollment file are generally the same as with the previous enrollment files (distributed February 10 and February 24). Steps include:

- Enroll any individuals that appear on this file and do not currently appear on the plans enrollment/eligibility files
- Add LIS eligibility for any member showing LIS eligibility (copay category of one through four) on this special file but not reflecting LIS eligibility on the plans enrollment/eligibility files
- Update LIS eligibility information if the LIS copay level or premium subsidy level is more favorable to the member than the copay or premium level currently on the plan enrollment and eligibility files. The copay/premium hierarchy, from most to least favorable, is:

Copay category	Premium Subsidy Percentage
3	100
2	100
1	100
4	100
4	75
4	50
4	25
0	0

Plans **SHALL NOT** remove LIS eligibility or cause a beneficiary to have a less favorable premium or copay based solely on information from this file.

Future Routine Disenrollments

The intent of the special enrollment reconciliation process is to execute a one-time synchronization of plan systems with CMS systems while ensuring that beneficiaries are enrolled in the plan of their choice. Plans must keep up with the routine disenrollment process in order to maintain synchronization with CMS systems. In addition to following these instructions for this special one-time activity, plans must continue to process disenrollment and enrollment cancellation transactions received from CMS. CMS is routinely processing these transactions and communicating their results to plans via the weekly TRRs. Plans should immediately process TRRs with transaction reply codes of 014 and 015 and distribute routine disenrollment correspondence to the beneficiary. The effective dates of these disenrollments are provided on the TRRs and will always be associated with a new start date in the receiving plan.

Attachments:
PDP letter
MA-PD letter